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# **A Novel Composite Material for Meniscus Replacement – Mechanical and Microstructural Evaluation**

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## **Abstract**

Medical grade silicone reinforced with nylon was fabricated into composites using compression moulding. Samples of both fibre and non-fibre reinforced silicones were mechanically evaluated. The composite with the optimum properties has its tensile modulus increased significantly from  $10.7 \pm 2.9$  MPa to  $114.6 \pm 20.9$  MPa when reinforced with 5% v/v nylon fibres. This value is within the circumferential tensile modulus of the native meniscus. Unlike the tensile modulus, the compressive modulus of the composite was found to reduce from  $2.5 \pm 0.6$  MPa to  $0.7 \pm 0.3$  MPa when fibres were incorporated; which is closer to the aggregate compressive modulus of the native meniscus. The meniscus, a complex and frequently damaged tissue, requires a substitute capable of reproducing similar biomechanical functions, and the developed composite material with comparable mechanical characteristics could serve as a useful step in the goal of producing meniscal replacement that gives satisfactory long term outcomes.

## **Introduction**

The meniscus of the knee is a C-shaped fibrocartilaginous structure situated between the condyles of the femur and the tibial plateaus. Meniscal injuries are among the most frequent injury at the knee [1]. Meniscal damage can occur through trauma and tears, for example during sporting activities, accident, or through degeneration of the meniscus cartilage in older people. Although tears originating in the meniscus have been repaired, this cartilaginous tissue does not heal properly due to lack of sufficient blood supply [2]. A meniscal replacement however has a distinguishable benefit in that it will both repair and replace especially in cases of complex tears [3]. Meniscal prostheses are essential as they have a place in restoring functions; they are helpful in increasing the contact area and lowering the contact pressure [4-6].

A wide range of synthetic polymeric composites have been investigated for use as meniscal replacements, among them being teflon, carbon fibre-polyurethane-poly(L-lactide), dacron, and polyurethane / PLLA composites [7-13]. A general limitation of these composites is their inability to provide long lasting protection to the articular cartilage and therefore none of these solutions is adequate for young energetic patients. Other problems associated with existing meniscal replacements include inability of the device to replicate the function of the native meniscus, wear of the prosthesis, unavailability, and possible immunological reactions. More recent developments being investigated involve the use of poly(vinyl alcohol) and polycarbonate-urethane reinforced with polyethylene fibres [14, 15].

The natural meniscus is a collagen fibre reinforced composite [16, 17] and therefore a composite material, specifically a fibre reinforced polymer composite, could be an ideal material substitute for meniscus prosthesis. Polymeric composite biomaterials are both anisotropic and heterogeneous [18] which are the properties of the natural meniscus [19].

Silicone materials have been widely used in biomedical applications. Their desirable elastic properties, chemical and thermal reliability, excellent biocompatibility, and notable biodegradability have made them acceptable [20, 21]. The successful outcome of implants made from silicone materials depends on whether the design closely imitates the properties of the parts intended for replacement [22]. The incorporation of reinforcements in silicone elastomers has been reported to improve its mechanical properties [21]. Nylon fibres, on the other hand, have been used for several applications owing to their outstanding physical properties, durability and chemical resistance. They are known for their high strength, low coefficient of friction, good abrasion and wear resistance, and are excellent materials for impact and heat resistance [23-25]. Nylon reinforced silicone elastomers have been used for various biomedical implants particularly in the area of prosthetic and orthotic applications. They are utilized for making below-knee socket inserts, distal end caps, shoe inserts and for lasting covers that enclose the flexible foam which houses the prosthesis [26, 27]. Nylon reinforced silicone elastomer sheeting has also been proven to be a suitable temporary material for abdominal closure [28].

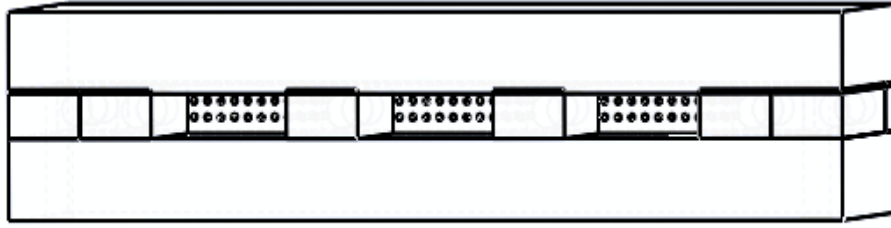
Due to the important biomechanical functions of the knee meniscus, it is of great significance that a replacement should perform similar functions such as providing mechanical support and stability during load bearing of the knee. It has been reported that some existing meniscal prostheses have been unsuitable as a result of their lower mechanical quality to that of the native meniscus [3]. In addition, for a meniscal implant material to sufficiently serve the role of natural meniscus and inhibit destructive changes in the articular cartilage, it should have similar mechanical properties to the native meniscus [29, 30]. Therefore the mechanical evaluation of an artificial substitute for the meniscus is of great significance since it can give an indication of its behaviour *in vivo*. The aim of this study was to design a novel meniscus prosthesis that has comparable mechanical properties to the native meniscus such that it will serve to eliminate articular cartilage degeneration. We have therefore developed composites consisting of two parts: the polymer matrix is medical grade silicone elastomer while the reinforcing fibres are nylon-6.

## **Materials and Methods**

### ***Design of the mould***

A custom mould was designed for the production of the mechanical test samples. The mould was designed such that the reinforcing fibres can be pulled through the mould and arranged horizontally at equal intervals as well as being held in tension. A 3-dimensional geometric design was made using SolidWorks (Dassault Systèmes, Vélizy, France) CAD (computer aided design) software from which the casting of the mould was done. The mould was made in different parts so as to allow easy removal of the samples after curing. Fig. 1 shows a cross section of the assembled

mould. The design included an enclosure for the mould in order to contain and prevent the matrix from spilling out of the mould.



**Fig. 1: Cross-sectional view of the mould for the mechanical test samples**

### ***Composite theory***

The quantity of the constituent materials was determined using composite theory known as the Rule of Mixtures. This technique is used to estimate composite properties based on the assumptions that (i) the fibres are parallel, continuous and evenly distributed within the matrix, (ii) the fibre and matrix are completely bonded together, (iii) longitudinal load generates equal strain in the fibre and matrix and (iv) the applied load in the fibre direction is collectively shared between the fibre and matrix.

The rule of mixtures predicts that the elastic modulus of the composite,  $E_c$ , is given in terms of the elastic moduli of the matrix,  $E_m$  and the fibre,  $E_f$  by:

$$E_c = E_m V_m + E_f V_f$$

where  $V_m$  and  $V_f$  are the volume fraction of the matrix and fibre respectively.

### ***Silicone elastomers***

The medical grade silicones used are as follows: Silastic® biomedical grade enhanced tear resistant (ETR) silicone elastomers Q7-4720, Q7-4765 and Q7-4780 (Dow Corning Limited, Coventry, UK). The properties of the silicones are shown in Table 1 as stated in the supplier's data sheets.

**Table 1** Typical properties of the different grades of silicone elastomers and the nylon fibre

| Material property                         | Q7-4720 | Q7- 4765 | Q7- 4780 | Nylon fibre |
|---|---------|----------|----------|-------------|
| Durometer Hardness - Shore A <sup>a</sup> | 23      | 65       | 77       | –           |
| Tear Strength (kN/m)                      | 32      | 45.1     | 41.7     | –           |
| Tensile Strength (MPa)                    | 9       | 8        | 7.8      | –           |
| Density (kg/m <sup>3</sup> )              | 1110    | 1200     | 1200     | 1150        |
| Elongation (%)                            | 1310    | 900      | 660      | –           |
| Elastic Modulus (GPa)                     | –       | –        | –        | 3           |
| Breaking load (kg)                        | –       | –        | –        | 24.9        |
| Melting point (°C)                        | –       | –        | –        | 220         |

<sup>a</sup> Durometer is generally used as a measure of hardness in elastomers. The Shore A scale is used for 'softer' materials like elastomers.

### ***Silicone blending***

The elastomers were supplied in two parts, A and B, combined in equal proportions by weight. Parts A and B were mixed together on a twin-roll mill (Winkworth Machinery Ltd, UK). As recommended by the supplier, part B was first softened on the twin-roll mill until it became a thin fine sheet, after which part A was gradually added into part B. The blended silicones of parts A and B were then collected from the mill using a pair of tongs and placed back into the mill for another round of mixing. This process was repeated several times until the two parts were completely blended as one mix.

### ***Nylon fibres***

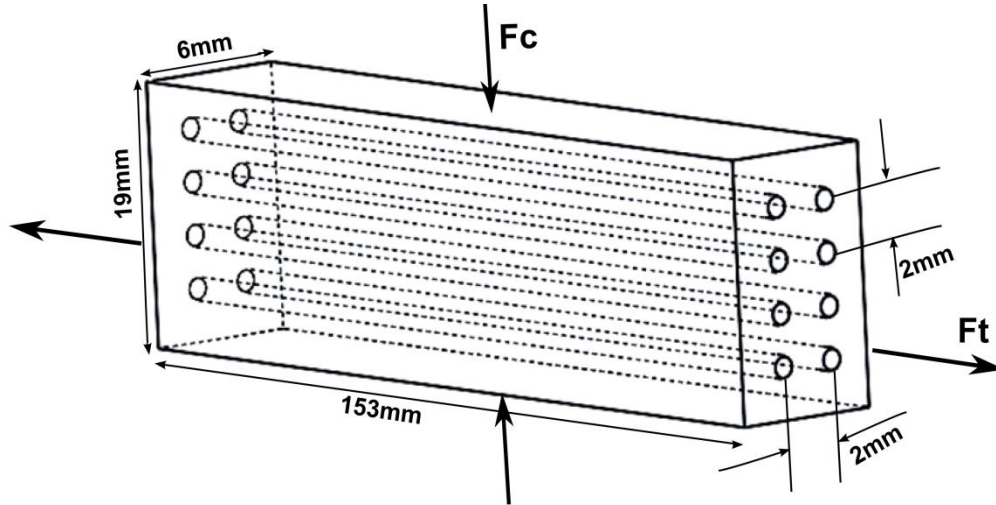
A 5% fibre volume fraction of 0.6 mm diameter nylon-6 (Fosters of Birmingham, Birmingham, UK) was used. Using Visual Studio 2010 (Microsoft, Redmond, Washington, USA), a C# 4.0 program was written to compute possible values of fibre diameter, fibre length and the number of fibres which would give the required fibre volume based on the rule of mixture calculations. The choice of the fibre diameter was then made considering the sample geometry that fits into the testing machine and gives the most feasible and realistic number of fibres. The material properties of the nylon-6 used are shown in Table 1.

### ***Arrangement of fibres***

The fibres were manually pulled through the holes in the mould from one end to the other. Each fibre was held tightly in order to keep it in tension while the last fibre was dragged across a screw and tightened until the fibres were no longer slack. The fibres were arranged prior to the composite preparation as it was observed that leaving the fibres in the mould caused them to sag.

### ***Composite preparation***

The composite material was prepared using the combinations of the different silicones and the nylon fibres. Having put in the fibres, the mould was filled with the mixed silicone and thereafter fixed into its enclosure. The rectangular cuboid (153 x 19 x 6 mm) samples (Fig. 2) were cured in a pre-heated hydraulic hot press (Moore E1127, Birmingham, UK) at 116°C for 3 h. The mould was allowed to cool for 24 h after which the samples were removed. The same process was followed for fabricating samples containing 100% polymeric matrix.



**Fig. 2: Schematic view of the fabricated mechanical test piece showing the arrangement of the fibres and the direction of the tensile testing,  $F_t$ , along the fibres while the compression testing was carried out perpendicular to the fibre direction,  $F_c$**

### ***Mechanical evaluation***

Both tensile and compression testing were performed using a Zwick/Roell Z030 material testing machine (Leominster, Herefordshire, UK). Rectangular cuboid shaped (70 x 19 x 6 mm) specimens were cut and tested in tension,  $F_t$  (Fig. 2). Each specimen was tested at a crosshead speed of 12 mm/min. Compression tests,  $F_c$  (Fig. 2), were carried out with cubic (6 x 6 x 6 mm) specimens at a crosshead speed of 5 mm/min. The tensile and compressive moduli were calculated from the slope of the initial linear region of the stress–strain curves recorded. These tests were also performed on 100% silicone elastomers. Four specimens were used in each of the tests. All the results were computed as mean  $\pm$  standard deviation and with Excel software (Microsoft, Washington, USA) the unpaired Student's t-test was used to assess the data statistically for significant difference at  $p < 0.05$ .

### ***Microstructural analysis***

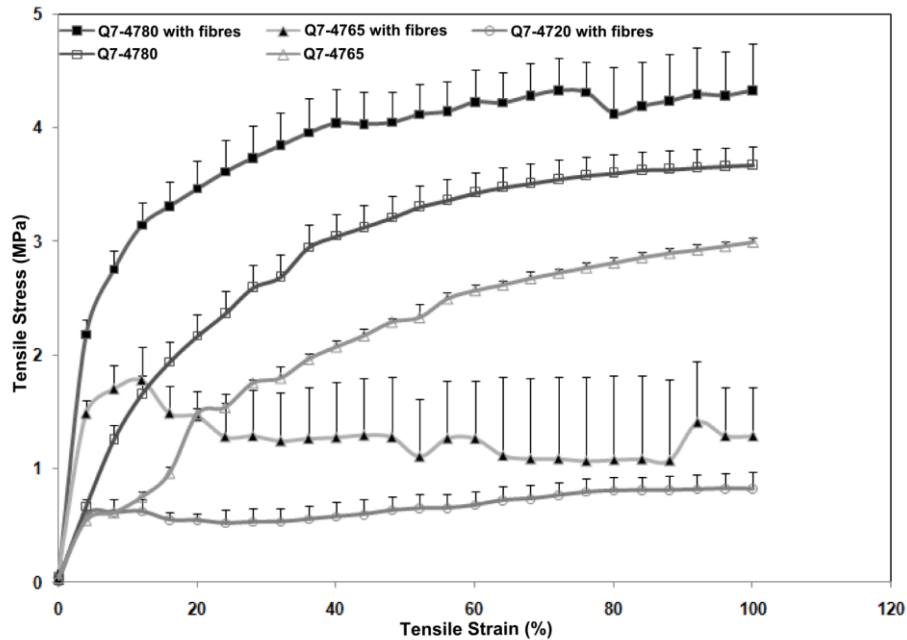
With the aid of a Wild M400 (USA) light microscope the distribution and alignment of the fibres in the composites were observed, while a FEI XL-30 FEG model environmental scanning electron microscope (ESEM) was used to further establish the fibre alignment in the composite.

## **Results**

### ***Mechanical properties***

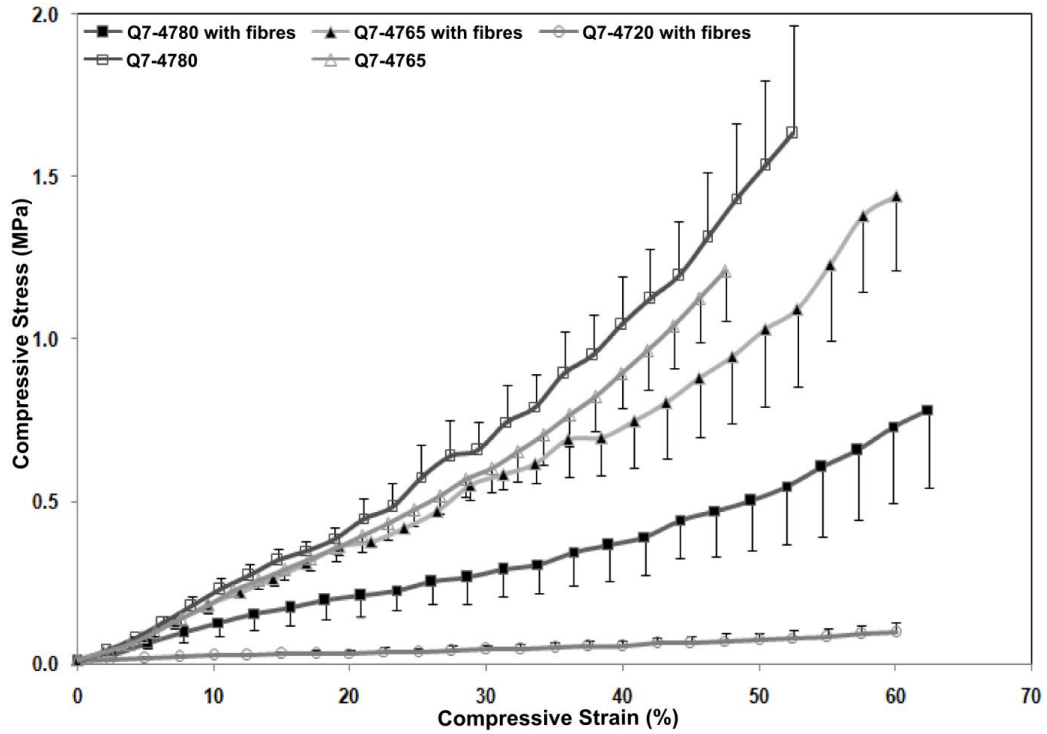
The stress-strain plots for both tension and compression tests for the silicones and their nylon reinforced composites are shown in Figs. 3 and 4 respectively. The stress versus strain curves for the tension tests represent the behaviour of the silicones and their composites up to 100% strain, these curves displayed a linear pattern at low strains. Thereafter, a considerable change occurred in the slope presenting a non-linear behaviour that was sustained until the composites finally failed beyond 100% strain. The unevenness seen in the curves of Q7-4780 and Q7-4765 composites is due to

the slippage of the fibres during extension. The composite of Q7-4765 exhibited a higher stiffness than its unreinforced counterpart up to 12% strain and the changes observed beyond this strain could suggest that the bonding between the matrix and the fibres had begun to break. The average values of the tensile moduli, tensile strengths and the compressive moduli of the silicones and their nylon reinforced composites are shown in Fig. 5. Although the tensile strengths obtained for the silicones were lesser than those quoted in the manufacturer's data sheet, the average tensile strength of the Q7-4780 increased with fibre addition while a contrary trend was observed with Q7-4765. However, statistically the fibre addition was found to be significantly different for Q7-4765 composite unlike for Q7-4780 silicones reinforced with fibres. Generally, the tensile and the compressive moduli increased significantly in all the composites combination with the addition of fibres. In particular, the tensile moduli of Q7-4780 and Q7-4765 composites were significantly influenced with the addition of fibres from 4% to 100% strain. The optimum tensile modulus was observed with composites of silicone elastomer Q7-4780 which increased from  $10.7 \pm 2.9$  MPa for 100% polymeric matrix samples to  $114.6 \pm 20.9$  MPa for composites with reinforced fibres. Its compressive modulus on the other hand reduced from  $2.5 \pm 0.6$  MPa to  $0.74 \pm 0.3$  MPa for samples without fibres and with fibres respectively. It was observed that after compression the Q7-4780 (with and without fibre) returned to their original shapes while the other silicones and their composites remained permanently deformed. The Q7-4720 without fibre was not tested (i) due to its soft texture and (ii) the tensile modulus obtained when reinforced with fibres was far below that of the native meniscus. The curve of the stress-strain graphs for both tension and compression revealed an elastic behaviour similar to that exhibited by the human meniscus tissue.

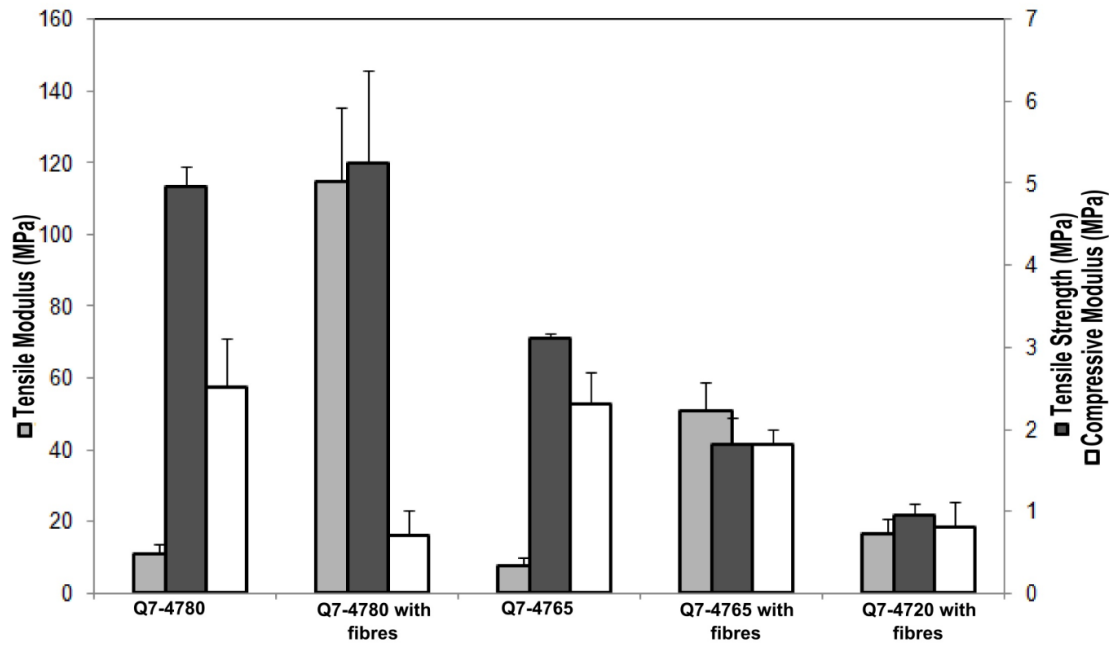


**Fig. 3: Tensile stress–strain plots for the different silicones and their nylon reinforced composites. Average values of tensile stress have been plotted against tensile strain. Error bars signify the standard deviations, two sided error bars implied but only the positive error values (top bars) are shown to prevent overlapping that may lead to confusion**





**Fig. 4: Compressive stress–strain plots for the different silicones and their nylon reinforced composites.** Average values of compressive stress have been plotted against compressive strain. Error bars signify the standard deviations, two sided error bars implied but only the positive error values (top bars) are shown for Q7-4780 and Q7-4720 with fibres, while negative error values (bottom bars) are shown for Q7-4765, Q7-4765 with fibres and Q7-4780 with fibres to prevent overlapping that may lead to confusion



**Fig. 5: Tensile and compressive properties of the silicones and their nylon reinforced composites. The average values of tensile moduli, tensile strengths and compressive moduli have been plotted against the different silicones and composites. Error bars signify the standard deviations, only the positive error values (top bars) are shown**

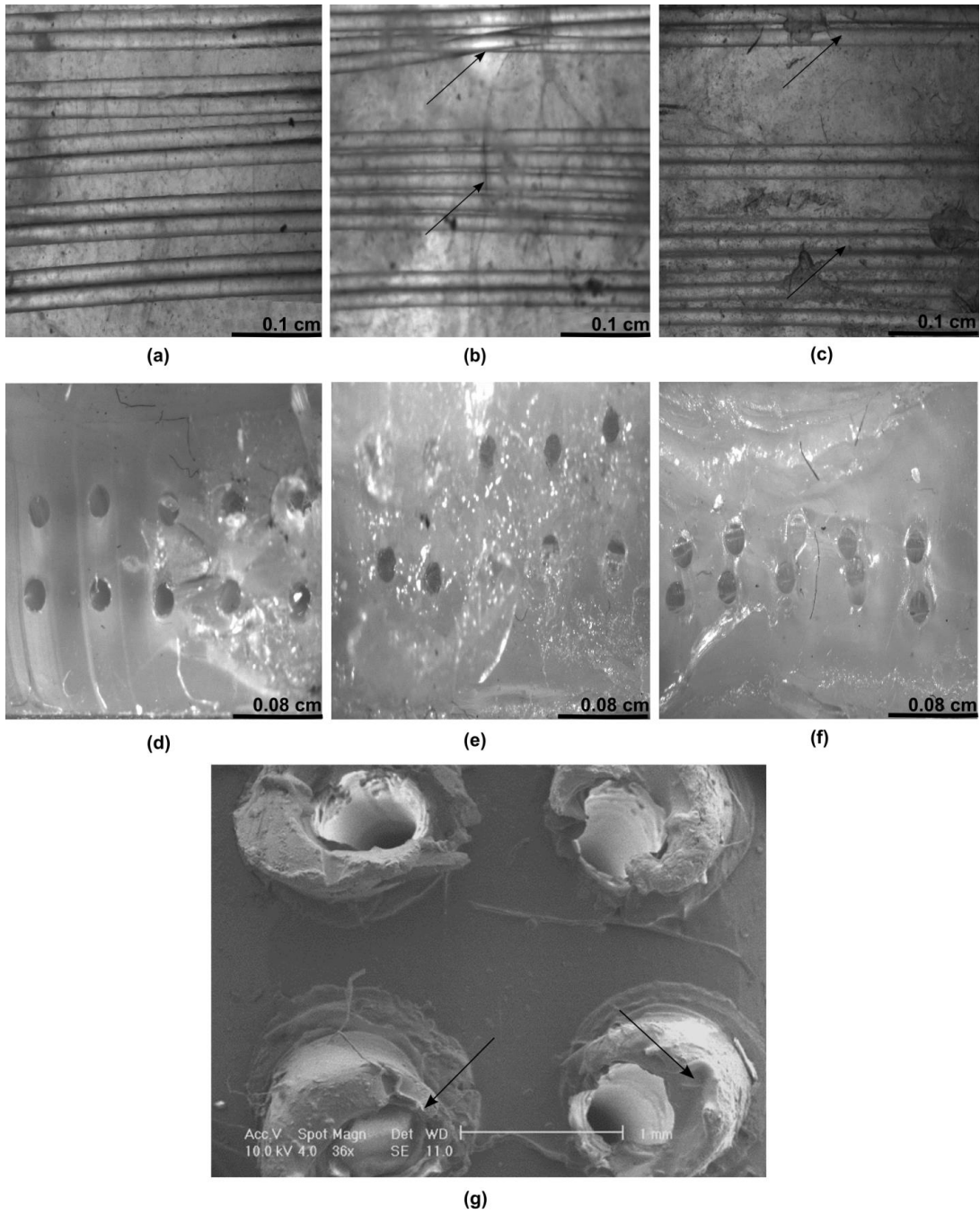
### ***Microstructural analysis***

The photomicrographs from the light microscope are presented in Figs. 6(a)-(d). The arrangement of the fibres in the composites of Q7- 4780 were almost uniformly distributed and at equal intervals to one another, as illustrated in Fig. 6(a). This observation was further established after viewing a cross section of the same sample under the same microscope, shown in Fig. 6(d). An examination under the ESEM as portrayed in Fig. 6g made this apparent. This showed the distribution of the nylon fibre within the silicone matrix. These fibres were arranged proportionately parallel to one another. Adjacent to the fibres are the formed rings of silicone-nylon fibre interface, depicted with the arrows. The distribution of the fibres in the composites of Q7- 4765 and Q7- 4720 are somewhat different, some of their fibres were skewed (Figs. 6b and 6c). The cross section of these samples (Figs. 6e and 6f) confirmed the differences in the uneven distribution of the fibres.

### **Discussion**

The knee transmits significant forces of up to 3-5 times body weight, of which the meniscus is known to carry anywhere between 45-75% of such load [19, 31-33]. This increases the contact area thereby shielding the underlying cartilage from experiencing high compressive stress [1, 34]. A meniscal replacement possessing similar biomechanical behaviour therefore is expected to support recurrent stress from the femoral condyle during flexion-extension motions

[35]. Furthermore, its load distribution capabilities are crucial so as to spread the load over a wide area such that the joint space is preserved.



**Fig. 6:** Micrographs showing the arrangement and alignment of the fibres within the composites of (a) Q7-4780 (b) Q7-4765 (c) Q7-4720. A cross sectional view of the arrangement and alignment of the fibres within these composites is shown for (d) Q7-4780 (e) Q7-4765 (f) Q7-4720. Scanning electron microscope observed for the cross section of composite of (g) Q7-4780

The mechanical performance of materials plays a major role in materials development. This is used for quality assessment and quality guarantee, to predict the materials behaviour under operating conditions different from those of the test and also utilized in computations during design [36]. This is particularly relevant to composites designed for load-bearing applications.

In this work we have fabricated composites of medical grade silicone elastomers reinforced with nylon fibres for replacing a meniscus. The excellent mechanical properties and biocompatibility of silicones coupled with nylon's notable physical properties and durability makes the developed composite a potentially exceptional and desirable replacement for the meniscus. One of the causes of the failure of meniscal devices is the incorrect choice of material selection used in their design. This lack of required material properties eventually leads to breakage, wear and tear. A material that will serve as a replacement for the meniscus must be able to accommodate high stresses and hence the need to have mechanical properties similar to that of the native meniscus.

In the nylon reinforced composites, an increase in the tensile modulus was observed as compared to their unreinforced analogue, and this follows a similar trend as described by a previous research group [14]. In comparison with the composite of Q7-4780 which had the highest tensile modulus, Q7-4765 had a lower modulus of approximately 43% while that of Q7-4720 was the least at approximately 15%. This is not surprising though considering the slippage of the fibres in both composites, leading to the clustering together of some of the fibres, as seen in the arrows on Figs. 6b and 6c, where some were even knotted. The lower modulus of Q7-4765 and Q7-4720 composites relative to Q7-4780 may be due to the method of manufacturing introducing some imperfection thereby hindering efficient stress distribution and transmission from the matrix to the fibres.

The tensile modulus obtained from the 100% Q7-4780 silicones was  $10.7 \pm 2.9$  MPa which increased appreciably by a factor of 10 when it was reinforced with nylon fibres. The optimum tensile modulus recorded in the Q7-4780 composite can be largely attributed to the relatively well aligned and almost evenly distributed nylon fibres that strengthened the matrix. This is also due to the increase in the fibre periphery in contact with the matrix, enriching the bonding of the fibre to the matrix [37]. However, based on the rule of mixtures, we anticipated a higher tensile modulus of 152.85 MPa for this composite material. This difference can partly be due to imperfect bonding that existed between the nylon fibres and the silicone elastomer. Additionally, the changes in the orientation of the fibres as a result of the manufacturing route may affect the mechanical behaviour of the composite [36], for example the pressing involved during the compression moulding of the test samples may be responsible for displacement of some of the fibres from their original position. The mechanical characteristics of composites are ultimately determined by the interfacial bond strength between the fibre and the matrix which is subject to type, shape and texture of the fibre surface. Fibre arrangement in composites influences their properties and randomly placed fibres have been reported to further enhance service performance [38].

Although the best nylon-silicone blend attained with Q7-4780 was lower than the calculated value, it is within the range obtained for the circumferential tensile modulus of the human meniscus, which is between 58 and 295MPa [38], after which our samples were modelled after. The longitudinal laying up of the fibres was patterned after the arrangement of the collagen fibres in the central layer of the native meniscus, where the majority of these fibres are concentrated. This outcome makes this composite a potentially desirable substitute for a replacement for the meniscus. The tensile strengths of the silicones were lower than those from the manufacturer's data sheets. This could be as a result of the different sample shape and size used and also the mode of testing employed. This comparison could not be adequately made as there was no information on these variables. The average tensile strength of the Q7-4780 increased with fibre reinforcement while the reverse was the case with Q7-4765, possibly because of the composite sample property since tensile strength is a property of both the constituent materials and the composite samples being tested.

Furthermore, the compression ability of the prosthesis is critical to its performance, and this is because of the supportive role the meniscus play in knee joint stability [13]. The compressive modulus is a key feature that prevents the high stresses and distributes the compression forces exerted by the femur over a large area on the tibia. The menisci are believed to transmit about 50% and almost 85% of the knee compressive load in extension and in 90° flexion respectively [39, 40]. This is accomplished by the peculiar longitudinal arrangement of their collagen fibres that create a resistance against the hoop stresses generated during load bearing that tends to extrude the menisci from in-between the femur and tibia. Unlike the tensile modulus, the compressive moduli of the composites were found to reduce drastically when reinforced with fibres. The lowest value was measured for the composite of Q7-4780 which decreased from  $2.5 \pm 0.6$  MPa to  $0.7 \pm 0.3$  MPa when fibres were incorporated. Although this value is higher than the aggregate compressive modulus of the native meniscus, which is 0.22 MPa [41], this reduction suggests that nylon reinforced silicones can be fashioned to mimic the desired properties for the native meniscus.

This composite has shown promise as a favourable material that could serve as a replacement for the meniscus. With this encouraging result further work is underway to develop the meniscus prototype based on our design of the wedge-shaped native meniscus from this composite material and carrying out mechanical testing in order to predict their characteristic behaviour *in vivo*.

## **Conclusion**

Medical grade silicones reinforced nylon composites have been developed and their mechanical characteristics examined. In general, it was observed that fibre reinforcement is a feasible method of mechanically improving the properties of the composites particularly the tensile moduli. Nylon reinforced silicones may be able to mimic the distinctive characteristic load sharing and distribution of the human meniscus hence it can be a viable artificial meniscus.

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